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COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFICE
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David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

NOV 11 2003

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,070,080 was filed on May 14, 2003,¹ under 35 U.S.C. § 156. It is noted that an application for patent term extension of U.S. Patent No. 4,937,234 was also filed based upon the regulatory review of the product Neutersol® (zinc gluconate).

The assistance of your Office is requested in confirming that the product identified in the application, Neutersol®(zinc gluconate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Grace J. Fishel
11970 Borman Drive, Suite 220
St. Louis, MO 63146

¹It is noted that the application states that the date was a day later.